

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

PATRICIA WOLFORD,

Plaintiff,

v.

Civil Action No. 2:12-cv-00835

BOSTON SCIENTIFIC CORP.,

Defendant.

MEMORANDUM OPINION AND ORDER
(Defendant's Motion for Partial Summary Judgment)

Pending before the court is Defendant Boston Scientific Corp.'s ("BSC") Motion for Partial Summary Judgment on Plaintiff Patricia Wolford's Punitive Damages Claim and Memorandum in Support ("Motion") [Docket 46]. As set forth below, BSC's Motion is **DENIED**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 70,000 cases currently pending, approximately 15,000 of which are in the Boston Scientific Corp. MDL, MDL 2326. In an effort to efficiently and effectively manage this massive MDL, I decided to conduct pretrial discovery and motions practice on an individualized basis so that once a case is trial-ready (that is, after the court has ruled on all *Daubert* motions and summary judgment motions, among other things), it can then be promptly transferred or remanded to the

appropriate district for trial. To this end, I ordered the plaintiffs and defendant to each select 50 cases, which would then become part of a “wave” of cases to be prepared for trial and, if necessary, remanded. (*See* Pretrial Order # 65, *In re Boston Scientific Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-002326, entered Dec. 19, 2013, available at <http://www.wvsc.uscourts.gov/MDL/boston/orders.html>). This selection process was completed twice, creating two waves of 100 cases, Wave 1 and Wave 2. Ms. Wolford’s case was selected as a Wave 1 case by the plaintiffs.

Plaintiff Patricia Wolford was surgically implanted with the Pinnacle Pelvic Floor Repair Kit (the “Pinnacle”) on December 18, 2008. (Am. Short Form Compl. [Docket 10] ¶¶ 8, 10). She received the surgery at a hospital in Orlando, Florida. (*Id.* ¶ 11). Her surgery was performed by Dr. Dorothy Odom. (*Id.* ¶ 12). The plaintiff claims that as a result of implantation of the Pinnacle, she has experienced multiple complications, including “[p]roblems urinating and problems with bowels, uncontrollable urinating, very painful intercourse, numerous surgeries to remove mesh from skin, cannot have intercourse at all because of pain, sharp pains in vagina.” (*See* Pl. Fact Sheet, Ex. T [Docket 46-2], at 6). She brings the following claims against BSC: strict liability for manufacturing defect, failure to warn, and design defect; negligence; breaches of express and implied warranties; fraudulent concealment; and punitive damages. (Am. Short Form Compl. [Docket 10] ¶ 13).

II. Legal Standards

A. Partial Summary Judgment

A partial summary judgment “is merely a pretrial adjudication that certain issues shall be deemed established for the trial of the case.” Fed. R. Civ. P. 56 advisory committee’s note. A motion for partial summary judgment is governed by the same standard applied to consideration of a full motion for summary judgment. *See Pettengill v. United States*, 867 F. Supp. 380, 381

(E.D. Va. 1994) (citing *Gill v. Rollins Protective Servs. Co.*, 773 F.2d 592, 595 (4th Cir. 1985)). To obtain summary judgment, the moving party must show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not “weigh the evidence and determine the truth of the matter.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some “concrete evidence from which a reasonable juror could return a verdict” in his or her favor. *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere “scintilla of evidence” in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105 F.3d 188, 191 (4th Cir. 1997).

B. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases such as this. The choice of law for these pretrial motions depends on whether they involve federal or state law. “When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however,

the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation.” *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). In cases based on diversity jurisdiction, the choice-of-law rules to be used are those of the states where the actions were originally filed. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) (“Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied.”); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010).

Here, the action was originally filed in Florida. (Compl. [Docket 1]). Thus, the choice-of-law principles of Florida guide this court’s choice-of-law analysis.

These principles compel application of Florida law. “In an action for a personal injury, the local law of the state where the injury occurred determines the rights and liabilities of the parties, unless, with respect to the particular issue, some other state has a more significant relationship” *Bishop v. Fla. Specialty Paint Co.*, 389 So. 2d 999, 1001 (Fla. 1980) (quoting Restatement (Second) of Conflict of Laws (“Restatement”) § 146); *see also id.* (quoting Restatement § 145) (listing factors to consider when determining which state has the most significant relationship to a dispute).

Here, the implantation surgery that allegedly resulted in the plaintiff’s injuries took place in Florida. (Am. Short Form Compl. [Docket 10] ¶ 11). Accordingly, in the absence of a state with a more significant relationship to the underlying causes of action, Florida has the most

significant relationship to the occurrence alleged in this lawsuit and to the parties. Thus, I apply Florida's substantive law to the claims in this case.

III. Analysis

"A defendant may be held liable for punitive damages only if the trier of fact, based on clear and convincing evidence, finds that the defendant was personally guilty of intentional misconduct or gross negligence." Fla. Stat. § 768.72(2). "'Intentional misconduct' means that the defendant had actual knowledge of the wrongfulness of the conduct and the high probability that injury or damage to the claimant would result and, despite that knowledge, intentionally pursued that course of conduct, resulting in injury or damage." *Id.* § 768.72(2)(a). "'Gross negligence' means that the defendant's conduct was so reckless or wanting in care that it constituted a conscious disregard or indifference to the life, safety, or rights of persons exposed to such conduct." *Id.* § 768.72(2)(b). In *Owens-Corning Fiberglas Corp. v. Ballard*, the Florida Supreme Court expounded on the statute, finding that

[t]he character of negligence necessary to sustain an award of punitive damages must be of a "gross and flagrant character, evincing reckless disregard of human life, or of the safety of persons exposed to its dangerous effects, or there is that entire want of care which would raise the presumption of a conscious indifference to consequences, or which shows wantonness or recklessness, or a grossly careless disregard of the safety and welfare of the public, or that reckless indifference to the rights of others which is equivalent to an intentional violation of them[.]"

749 So. 2d 483, 486 (Fla. 1999) (quoting *White Constr. Co. v. Dupont*, 455 So. 2d 1026, 1029 (Fla. 1984), *receded from on other grounds by Murphy v. Int'l Robotic Sys., Inc.*, 766 So. 2d 1010 (Fla. 2000)).

The plaintiff's burden is even heavier for a punitive damages claim against a corporate defendant such as BSC. The plaintiff must show that the corporate officers, directors, or managers "knowingly condoned, ratified, or consented to such conduct," or that the corporation

itself “actively and knowingly participated in such conduct” or “engaged in conduct that constituted gross negligence and that contributed to the loss, damages, or injury suffered by the claimant.” Fla. Stat. § 768.72(3). The failure to make such a showing precludes punitive damages as a matter of law. *See Mercury Motors Express, Inc. v. Smith*, 393 So. 2d 545, 549 (Fla. 1981).

BSC contends that the plaintiff has not produced evidence of any BSC conduct that was so egregious as to warrant punitive damages. (Def.’s Mot. for Partial Summ. J. on Pl.’s Punitive Damages Claim & Mem. in Supp. (“Mem. in Supp.”) [Docket 46], at 15–16). As evidence that BSC “diligently followed all applicable rules, regulations, and industry standards,” it notes that the Pinnacle was submitted to the Food and Drug Administration (the “FDA”) prior to marketing, and that the FDA cleared the product with full knowledge of its potential risks and benefits. (*Id.* at 15). I decline to consider the FDA preclearance process in my judgment.¹ Next, BSC points out Dr. Odom’s testimony that the benefits of the Pinnacle surgery outweighed its risk, and that the procedure was the best option for Ms. Wolford’s prolapse. (*Id.*).

The plaintiff, on the other hand, relies on my decisions in *Hendricks v. Boston Scientific Corp.*, 51 F. Supp. 3d 638 (S.D. W. Va. 2014), and *Sanchez v. Boston Scientific Corp.*, 38 F. Supp. 3d 727 (S.D. W. Va. 2014). She argues that a reasonable jury could find that BSC’s actions were wanton, willful, or reckless because “BSC ignored a warning on the [Material Safety Data Sheet (the “MSDS”)] and failed to conduct clinical testing before selling its device.” (Pl.’s Resp. in Opp’n to BSC’s Mot. for Partial Summ. J. (“Resp.”) [Docket 60], at 13). Although

¹ As I explained in *Lewis v. Johnson & Johnson*,

Evidence regarding the 510(k) process poses a substantial risk of misleading the jury and confusing the issues. That a device has been given clearance through the FDA’s 510(k) process is not relevant to state tort law. Admission of any evidence regarding the 510(k) process runs the risk of misleading the jury to believe that FDA 510(k) clearance might be dispositive of the plaintiffs’ state law claims. The prejudicial value of evidence regarding the 510(k) process far outweighs its probative value.

991 F. Supp. 2d 748, 754 (S.D. W. Va. 2014).

Hendricks and *Sanchez* did not concern Florida law, my reasoning in those cases applies with equal force here.

As in *Sanchez*, the MSDS at issue here warned BSC not to implant the material into the human body. (MSDS [Docket 60-5], at 1). Specifically, the warning provided:

MEDICAL APPLICATION CAUTION: Do not use this Chevron Phillips Chemical Company LP material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

(*Id.*). Despite this warning, BSC used the Chevron Phillips polypropylene in the Pinnacle device.

Additionally, the plaintiff references the written agreement between BSC and its polypropylene supplier (“the Agreement”), which cautioned BSC to make its own determination of the safety and suitability of the polypropylene material in its products. (Resp. [Docket 60], at 14). The Agreement provided:

BEFORE USING ANY PSPC POLYPROPYLENE PRODUCT, BOSTON SCIENTIFIC IS ADVISED AND CAUTIONED TO MAKE ITS OWN DETERMINATION AND ASSESSMENT OF THE PSPC POLYPROPYLENE PRODUCT FOR USE BY, FOR OR ON BEHALF OF BOSTON SCIENTIFIC. IT IS THE ULTIMATE RESPONSIBILITY OF BOSTON SCIENTIFIC TO ENSURE THAT THE PSPC POLYPROPYLENE PRODUCT IS SUITED TO BOSTON SCIENTIFIC’S SPECIFIC APPLICATION.

(Agreement [Docket 60-8], at PageID # 7118).

Despite the MSDS warning and the admonition from BSC’s polypropylene supplier to conduct its own tests, an internal BSC document indicated that BSC conducted no clinical studies on the Pinnacle before releasing it to the public. (*See* Pinnacle Clinical Risk/Benefit Analysis [Docket 60-1], at PageID # 7043).

In light of this evidence, I **FIND** that under a clear and convincing standard, a reasonable juror could find that by ignoring a warning on the MSDS and neglecting to conduct clinical studies, BSC is “guilty of intentional misconduct or gross negligence.” *See* Fla. Stat. § 768.72(2).

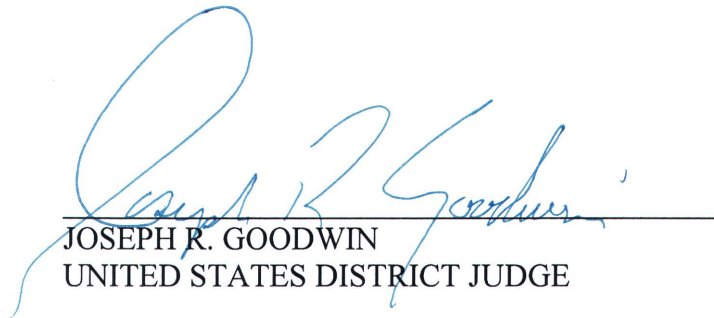
Accordingly, BSC's motion for summary judgment on the issue of punitive damages is **DENIED**.

IV. Conclusion

For the reasons discussed above, it is **ORDERED** that BSC's Motion [Docket 30] be **DENIED**.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 8, 2015



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE